Independent Review Board (IRB)

Policies and Procedures

Procedures Title	BMY Health IRB Policies and Procedures
Department	Independent Review Board, Research Unit, BMY Health Pakistan
Version	1.1
Previous Revision Date	22-03-2025
Current Revision Date	12-11-2025
Changes	Ethics Review Team, Scientific Review Team Evaluations combined under one Independent Review Board for coordination on projects, adding a third review process for operational integrity.

Purpose

The BMY Health IRB serves as an independent public health and research ethics board to ensure that all public health[1] and research projects demonstrate scientific integrity, ethical integrity, and operational integrity, protecting participants' welfare while generating meaningful, reliable knowledge. Policies and procedures have been developed to promote consistency, fairness, and objectivity across all project evaluations.

Structure and Function

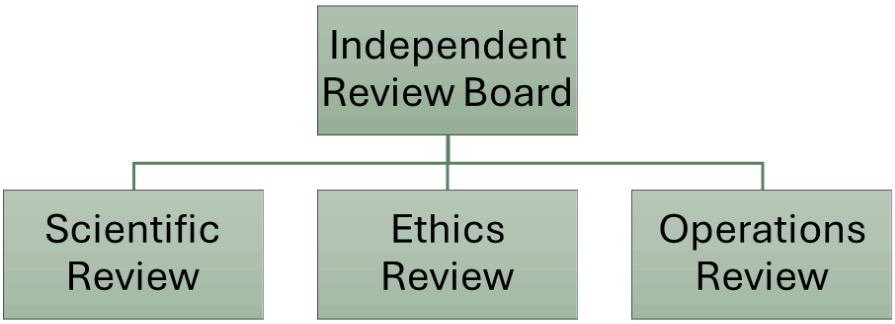
The IRB is structured into three independent review streams for 2 functions:

1. **Scientific Review (SR):** Conducts review before ethics screening, to assess scientific rigor, project or research design robustness, and methodology, prior to ethics review. Multidisciplinary experts provide an unbiased perspective.

[1] At BMY Health Pakistan, IRB will not only screen research for ethics, but other public health projects that depend on goodwill, altruistic labor, donated funds, or community trust, requiring additional layers of protection to maintain legitimacy and avoid exploitation.

2. **Ethics Review (ER):** Evaluates ethical integrity after scientific clearance, focusing on participant welfare, justice, beneficence, and risk mitigation.

3. **Operations Review (OR):** Screens projects for operational integrity, including feasibility and efficiency, ensuring the public health project or research can be implemented successfully and ethically.



IRB review panel will include members outside the research team/ project, independent of any conflicts of interests. IRB panel will serve two functions as below:

1. **Public Health Ethics Board,** with a review panel of public health and subject experts, ethicists, and management experts, for screening of public health & service delivery projects fulfilling criteria of review.
2. **Research Ethics Board**, with a review panel of research methodologists and subject experts, ethicists, and project management experts, for screening of research projects.

Scope

IRB services apply for public health or health research (clinical/ public & allied health research) projects of all designs, initiated by employed staff/ interns at BMY Health or associate members. Other interested organizations can also outsource IRB services to BMY Health under formal agreements for independent evaluation of their projects. BMY Health can also collaborate with external IRBs that meet our standards for higher impartiality of reviews. OR reviews will include at least one member from the relevant organization (outside the research team) to contextualize operational feasibility without compromising independence.

Workflow

Step 1 Scientific Integrity Review

1.A: Subject Expert Review

Done by clinicians, field specialists, and academic experts.

Focus: Topic validity, tool relevance, field feasibility, and scientific novelty.

1.B: Study Design/ Public Health Expert Review

Done by biostatisticians and methodology experts.

Focus: Study design appropriateness, sample size justification, variable clarity, and statistical analysis plan.

Step 2. Ethical Integrity Review

Done by Bioethics experts

Focus: approving project based on risk/ benefit balance in the study (for participants, researchers and societies), data safety, monitoring and follow-up needs of IRB

Step 3. Operational Integrity Review

Done by HR department/ or any project management expert aware of organization resources and context

Focus: Operational feasibility (achieving project goals within organization's limitations), operational efficiency (optimizing project with best use of organization's resources & strengths)

Final Consolidated decision by IRB Chair

Submissions for Review:

1. Research projects will be submitted using the link. *Use Password: BMYHEALTHERC to open the link.* BMY Health IRB will review the research proposals of staff/ members affiliated with BMY Health organization. This includes research on data collected by BMY Health Services Unit, any data collected in community, private clinics, primary/ secondary healthcare facilities lacking IRBs, or other healthcare organizations that assigned jurisdiction to BMY Health IRB for ethics approval of their research. Organizations can outsource IRB service to BMY Health through official agreements.
2. For Public health projects other than research, use this template and email submission at admin@bmyhealth.com.

Scientific Review (SR) Procedures

1. After submission of a proposal, IRB chair invites two scientific reviewers to screen the project, one as subject matter expert and other as study design/ methodology expert.
2. **Objective:** The primary objective of SR is to ensure scientific validity of the project.
3. **Review Guidelines for SR Team:**

   3.1. Subject Matter Experts: Subject experts should assess whether the study addresses a valid and meaningful topic for patients or the health system, ensuring that all operational definitions, such as measurement criteria, disease classifications, or diagnostic standards, are accurate and appropriate. They should also review the validity of the proposed tools (questionnaire, proforma, or diagnostic instrument) and assess if it truly measures what it intends to measure. Finally, reviewers should comment on the apparent feasibility of conducting the study in real clinical or field settings, accounting for factors such as disease prevalence, patient accessibility, cultural sensitivities, social stigma, and historically low response rates in sensitive research areas.

   3.2 Study Design: Study design/ research methodology reviewers should evaluate whether the study design is appropriate for answering the research question and confirm that the data collection tools, proformas, methods, timings, sites, and recruitment strategies are both scientifically sound and culturally appropriate. They should ensure the inclusion and exclusion criteria are correctly defined, the sampling technique is valid and clearly explained, and the sample size is accurately justified. Reviewers must also assess whether the data types and planned analyses are correctly detailed and verify that the overall methodology is coherent, internally aligned, and logically structured.

Ethics Review (ER) Procedures

1. The ER process can start after scientific reviewers have reviewed the project. In case no major changes are being suggested by the scientific team or if the project is low risk, the ER team can start in parallel but where significant changes are required in design that can require further confirmation from the scientific reviewers, ER Team should wait for researchers to do the changes before starting review. Make sure that no project receives ER approval before scientific validity is confirmed. All reviewers should keep liaison for effective screening of the project.
2. **Objective:** The primary objective of an Ethics Review (ER) is to protect the welfare of human subjects in research in accordance with the principles of Declaration of Helsinki and the Belmont Report. Additionally, BMY Health ER team is committed to safeguarding the welfare of researchers as outlined in this document.
3. **Review Steps:** The ER reviews a project in the following steps.
    a. An initial assessment of the level of risk to determine what level of scrutiny the review requires.
    b. Initial review for ethical acceptability of project design.
    c. Continuing review for data safety and audits, extending to ethical dissemination of results and compliance with ICMJE criteria for publication ethics and ending with completion of retention period for research records.

4. **Review Guidelines for ER Team**

5.1. Risk Assessment and Review Level: Automated preliminary categorization of risks, followed by Chair confirmation for decision on Review level. Based on project need, reviewer/s will be assigned by Chair. Reviewers will also confirm the review level and give feedback where important.

5.2. Initial Review Criteria for Research: BMY Health ethics review process uses National Bioethics Committee guidelines and international guidelines for review of studies under different categories. The key principles from Declaration of Helsinki and Belmont Report guide our process, emphasizing on participant welfare, justice, risk benefit balance, informed consent, data confidentiality and cultural sensitivity. Key points for assessment include exposure of participants to risks (physical, emotional, social/ economic, data disclosure risk), amount of risk (less than minimal risk, minimal risk, more than minimal risk) confirming the level of review, considerations in informed consent, recruitment materials, care in subject selection, equal opportunity of benefits for population groups, balancing harms and benefits in study overall, and care of community norms[2]. Review also includes questions for

[2]Research proformas circulating in public have the potential to influence society trends. Our BMY Health Pakistan IRB cares for community norms in the country of data collection and confirms that data collection tools/ methods are sensitive to social norms and are not designed in a way that inadvertently influences any trends in short or long term, that are sacred/ deeply

researchers', societies', and host institution's risks. Relevant questions are included in the online IRB application for awareness of researchers and will be filled in by them as self-reported compliance with ethics, but all responses will be checked by the ER team with detailed review for confirming compliance with ethics. ER team may require changes to the protocol if the study does not present a favorable balance between the risks and potential benefits. The guidelines require careful scrutiny of data confidentiality and safety, determining whether additional protections are necessary and whether data can be shared publicly in line with journal policies. Reviewers also inform of the need for continued ethics oversight, defining monitoring requirements, audit considerations, and publication-related ethical points which they screen in post-research audits. Finally, reviewers consider any further approvals or consultations needed before data collection, alongside any additional ethical concerns relevant to the research context.

5.3. Research including Validated Tools: A commonly used approach in our research is using validated scales for measuring some health phenomenon/ behaviors/ disease screening etc. In such projects, researchers have an ethical responsibility to share scoring/ screening/ individual results with participants and to provide clear, appropriate guidance on next steps including referral pathways, counselling options, and support resources. Participants retain the right to decide whether they wish to receive partial or complete results of their health, predictive, or genetic information, and this choice must be incorporated into informed consent. Results must be communicated in clear, non-technical language. In case of genetic screenings, findings may affect relatives who are not part of the study and participants' choice should be asked for sharing information. Explain the implications during informed consent. Plans for sharing findings, and post-research responsibilities such as referral and care, thresholds for disclosure and its inclusion in consent, must be pre-specified in the protocol and reviewed by the ethics team, consistent with CIOMS (2016) and WHO.

5.4. Review Criteria for Public Health Projects: Reviewers ensure that every submission is assessed for its public health necessity, proportionality, fairness, reciprocity, and respect for community welfare. Reviewers examine whether the activity demonstrates clear social value, minimizes risks, protects privacy, and avoids coercion or undue influence, following principles outlined by the Public Health Leadership Society (2002), the Nuffield Council on Bioethics (2007), and WHO's ethics guidance for public health practice (2016). They also evaluate

rooted in society based on their socio religious beliefs. One example is recording gender in more categories than what are considered acceptable in Pakistani society. It is advisable to allow only two categories "male" and "female" in the question of "gender", in line with our socio religious norms. In research where information about intersex by birth/ Khawaja sra is required, the term of "biological sex" may be written in the question instead of "gender" and 3 categories of "male", "female" and "intersex by birth" (not the term transgender) may be written. Such question maybe required in a study where biological sex can have influence over the study variable. Mostly research requires information of social role (gender) which can be either male or female (as persons who are Intersex by birth also have to choose between one of the two social roles of male/ female, as their social right and a right recognized in Islam (predominant religion in Pakistan); hence a third category for them is not needed in question of gender).

whether benefits and burdens are distributed justly, including attention to distributive, procedural, and relational justice, and whether vulnerable groups are protected from inequitable treatment. Consistency, transparency, and documentation of reasoning are required so that decisions remain objective, defensible, and aligned with established ethical standards.

Operations Review (OR) Procedures

1. This review can start after the ER reviewer has also provided their first review comments. or in parallel with other reviewers if minor revisions are being suggested or if the project is low risk. If revisions required by OR need a change in project design/strategies, IRB Chair will decide the need of SR or ER again.
2. **Objective:** Ensure operational integrity by assessing implementation feasibility and efficiency, enabling the project to generate meaningful knowledge ethically. [3]

3. **Review Guidelines for OR Team:**

   3.1. **Operational feasibility:** Reviewers will assess feasibility based on realistic planning in terms of timelines, budget, and manpower, ensuring that project goals can be achieved within the constraints of the organization (as known to the reviewer) and with particular attention to the actual feasibility of data collection, including expected response rates (as shared by researchers, or anticipated by subject experts). They will also review if contingency plans are in place for recruitment or workflow challenges to be addressed promptly, alongside clear governance structures and clarity of roles.

   3.2. **Operational efficiency:** It will be assessed depending on the effective use of available technology, optimized processes that minimize redundancy, and strong monitoring and quality-assurance mechanisms to ensure knowledge generation standards (the promised benefit for participants) are maintained throughout the project.

IRB administration team or chair will confirm all changes done by the researchers as required by 3 teams before conveying the final approval of the project.

Final review by the IRB Chair: This will include an assessment of review strength, and applicant's compliance with changes suggested. The chair can request more details from reviewers to confirm a decision. In case any changes in project design are required by OR after ethics clearance, the Chair will consult the SR team to confirm scientific validity, and review the ethical aspects again as needed, before the final decision of the project.

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[3] *The justification of research risks depends on the assumption that the project will produce meaningful knowledge, an outcome that requires realistic and efficient planning. Screening a project's operational strength and integrity therefore becomes an ethical prerequisite, equal in importance to scientific validity, for ensuring that useful knowledge can actually be generated. While feasibility and scientific reviews are widely recognized, the establishment of separate panels dedicated to each review domain, especially operational integrity, is not common. Creating distinct panels ensures that all review steps are mandatory, never overlooked, and conducted by members with the appropriate expertise, thereby improving the overall quality and reliability of the research process.*

IRB Meetings Frequency and Protocol

Initial Review

1. The IRB will hold an **online discussion scheduled** for approval/ disapproval/ changes in the project. At least five members from the IRB panel will have to review the research for full review including IRB chair, scientific reviewers, ethics experts, operational review team member, community member. For exempt and expedited review, the chair may 1-2 designate member/s from each team including Scientific Review, Ethics Review and Operational Review Teams. The meeting time will be scheduled and announced by the Chair of the IRB.
2. Members will give **timely review** online for exempt and expedited review, within 2-3 days of receipt of proposal. For timely review, IRB should confirm members' availability 10-14 days prior to the expected submissions. For full review of research involving more than minimal risk, all research team and panel will have a meeting online and researchers will justify how the benefits of research are more than the risks involved.
3. For research projects, reviewers will use REB Checklist for adding their review comments.
4. For public health projects other than research, reviewers will use PHEB Checklist.
5. Decision of a research approval will be taken with **consensus** of members. Any matter of controversy will be left to the Chair to decide. IRB teams will clearly convey all the concerns to the research team, with guidance on improving compliance with ethics.
6. The **supervisor** of the team should be present in the IRB meetings to lead discussion with the review team. Where the review of a project reveals technical mistakes, the supervisor should be asked to support the team in corrections. In case of gross technical mistakes related to scientific review (outside the domain of ethical review), the supervisor may be referred to training resources and evaluated before being assigned as supervisor in next projects.
7. All review processes should be completely **ethical** and at no step should be violating respect of applicants by derogatory remarks on style of writing or raising points that are not relevant to ethical consideration or study design, or by diverting from the objective of the IRB which is ensuring the scientific integrity, and welfare of human subjects and researchers, in an operationally valid design. It is not within the mandate of the IRB to assess a study based on the likelihood of publication. Also, it is not the responsibility of IRB to provide advice about alternative methods to answer the research question. Applicants should not be left in ambiguity on how to address gaps in design or prevent risks highlighted by IRB teams and suggestions should be given. Any guidance to improve compliance with ethics should be given in a suggestive style, avoiding an imposing/ enforcing style. Applicants may be given an option to follow suggestions of IRB or to brainstorm on their own how to prevent some highlighted risk where they're not convinced with ideas of reviewers. The project should be approved if the final proposal after discussion reaches scientific validity with a balance in risks and benefits, irrespective of whose suggestions were implemented.

8. If there's some **disagreement** between applicants and IRB on project approval, applicants can apply for reconsideration. If they are unable to resolve disagreement through deliberation or advice, the applicants may appeal the IRB decision by emailing to Chair. The chair must justify decisions in writing.
9. All feedback, whether written or verbal, must be shared constructively, with mutual respect. No judgmental or dismissive remarks should be given, the focus should be on guidance and solution-oriented suggestions. A **code of conduct policy for reviewers** is attached here.

10. The IRB review panel for a project will include members who are **independent** of the project team, free from any conflicts of interests/ biases with the team/ project. Any member having conflicts of interest with the project or team must openly disclose them to the Chair. Where a member contributed to the review and later joined the project team, the review will be done again excluding the member from the review panel and the member must inform the IRB upon joining the project team.

Continuing Review

1. Studies that require monitoring by a Data Safety Monitoring Board will be notified to be followed up by BMY Health **Data Monitoring Safety Board**. For other studies that do not require this monitoring, audit of data collection will still be done to ensure integrity and quality of data. The frequency of audits for continuous review depends on the risk levels of study.
2. **All studies are subject to continuing review** which extends to data analysis and ethical dissemination of the results, ensuring compliance with ICMJE guidelines for authorship, and BMY Health Rules in research collaboration. It is the responsibility of applicants to inform any changes or anticipated harm to participants during the research.
3. **Research records and data** will be maintained by BMY Health for all staff, interns, and members' projects reviewed by BMY Health IRB for a minimum period of three years. Researchers and team members leaving the project any time due to the end of employment/ collaboration will hand over all records and data to BMY Health and destroy any data at their end. Team staying till the end of collaboration will submit all data and records to BMY Health for organization records and will maintain soft copies at their end, discarding any hard copies to avoid any risk of accidental breach of participants' data.

Final Review/ Audit

Compliance with the ethics guidelines will be checked in the final audit at the end of project. The ethics member who reviews the project in the initial IRB review, should perform the final audit. A thorough and careful initial review will include points to guide their final audit too.

Link to submission for Audit: [Audit application] (for researchers)

Two letters should be given by the IRB team, one at the time of starting the project (IRB approval letter), and a second at the time of closing the project (IRB audit letter). Team leader should apply for the second letter at the time of closing the project and fulfill the audit requirements for issuance of the letter.

Accountability and Continuous Improvement of IRB

1. Though IRB is independent in making decisions about the ethical review of research, they remain accountable to the organization for **IRB operations** including appointment of IRB members, compliance with organization's policies, and carrying out operations in a timely and efficient manner.
2. The Board will keep a **record** of all proposals submitted for approval, meeting minutes, and approval letters.
3. **Organization policies** related to research ethics, including non-disclosure of intellectual properties, confidential information of organization or service users, and general code of conduct applicable to employees of BMY Health will apply to the consultants on panel also when working through the forum of BMY Health.
4. All communication between IRB members and the Research team will be handled through the **official communication channels** advised by BMY Health. In case communication is done through an unofficial channel due to unavoidable reasons, it should be documented and conveyed to the relevant persons.
5. In case any member of the IRB team is seen **violating rules**, witnesses must inform the Chair with proofs through email (contacts shared at the end of document). In case the Chairs are found violating rules, the CEO of the organization should be informed through email. Disciplinary action will be taken against IRB Members/ Chairs violating rules and involved in unethical practices specially related to not disclosing conflicts of interests with research team/ project under review, joining a research team where they served on review panel and not informing the Chair, or showing negligence in review process where the welfare of research participants is grossly compromised by not addressing clearly visible and preventable risks in the study.
6. BMY Health has developed anonymous feedback mechanisms to ensure that our IRB continues improving the processes. Feedback for IRB should be sought from the researchers with this form after completing their review process. The feedback will be periodically checked by the Director Research Unit and shared with the IRB team to generate discussion for improvement of processes.

7. BMY Health will incentivize research ethics training by paying members qualified in research ethics (certification and above) for every protocol review. Training resources and documents will be shared with the IRB team for their continuous learning and improvement.

IRB fee per protocol review (PKR):

Levels	Employed staff	Associate members	Non-members through organization partnerships
Expedited reviews	10,000	12,000	15,000
Full reviews	15,500	18,000	22,500

This review fee covers initial IRB reviews (SR, ER, OR reviews) and final IRB audit by ER team. 1 project review is free for interns and volunteers. Above fees apply to self-funded projects in Pakistan. Contact the IRB Chair for industry/ government funded project review fees.

IRB Panel 2025

Sr. No.	Member Name	Role in IRB	Relevant Skills/ Experience
1	Dr. Bushra Anwar **Director Health Research**, BMY Health	**Chair (IRB Administration)**	MBBS, FCPS Community Medicine, Applied Clinical Research Certification (McMaster University), Family Medicine Certification (DUHS), ICH-GCP, Biomedical research ethics (CIT), TCPS-2 certification (PRE Canada), Essential Skills in Clinical Research from Canadian College of Healthcare and Pharmaceuticals. Experience as In-charge Research Cell and IRB member at HITEC medical college
2	Dr. Yousaf Ali **Director Health Planning, BMY Health**	**Scientific Member (Public Health Subject Expert)**	MBBS, FCPS Community Medicine, Trained from AKUK, winner of research grant, experienced in many research and public health projects, Assistant Professor Community Medicine, Shaqra University, Saudi Arabia
3	**Prof. Farooq Azam Rathore**	**Ethics Member**	Master in Bioethics, extensive experience in research and bioethics, Professor in Rehabilitation Medicine, Pain Specialist, Combined Military Hospital Quetta Cantonment.

4	**Dr. Sarosh Saleem**	**Ethics Member**	PhD in Healthcare Ethics from Saint Louis University USA, Physician, Pediatric bioethics fellowship in the USA, Founder, Pakistan's First Bioethics Department, Actively presents on ethical issues globally
5	**Dr. Fareeha Farooq**	**Ethics Member**	MBBS, FCPS, CMT, and DHEP in Bioethics, Prof. Biochemistry, Islamic International Medical College, extensive experience in research.
6	Dr. Sana Siddiqui, **Assist. Prof. SZMC, Rahimyar Khan**	**Ethics Member**	MBBS, FCPS Community Medicine, Trained by BMY Health for screening protocols for compliance with research ethics, trained for 'Informed Consent' from Global Health Training Center, Assistant Prof. Community Medicine, Shaikh Zayed Medical College, RYK
7	Dr. Omera Naseer, **Senior Scientist, NIH**	**Scientific Member (Clinical Trials)**	MBBS, FCPS Community Medicine, FELTP, MS. Community Health and Nutrition, Winner of multiple grants from Pakistan and USA, experienced in clinical trials, trained in biomedical ethics by NIH USA
8	Muhammad Aatasam Naseer, **Economist**	**Scientific Member (Health Economics)**	Graduate in Economics from Cambridge University, UK, skillful in screening protocols for compliance with scientific norms, and cost effectiveness of research.
9	Muzammal Butt **Member Lahore Tax Bar Association**	**Non-Scientific Member (Law)**	B.Com, LLB, Registered Income Tax Practitioner, skillful in screening protocols for compliance with country laws.
10	Munira Nadeem	**Community Member**	MSc Psychology, expected to screen protocols for compliance with community norms and culture and represent the research participant perspective.
11	Dr. Owais Raza	**Scientific Member (Epidemiologist)**	MBBS, PhD Epidemiology, Assistant Professor at the School of Public Health, Dow University of Health Sciences. He served as Deputy Director of Research at PPHI Sindh, overseeing research activities across 22 districts of the province.
12	Dr. Tahani Waqar	**Scientific Member (Qualitative Research Expert)**	MBBS, Public Health Researcher and SRH Content Creator specializing in reproductive health education. Master Trainer of Post-Partum Family Planning from Aga Khan University Karachi, equipped to lead training programs and develop culturally sensitive health content.
13	Dr. Ubaid ur Rehman	**Scientific Member (Surgery Subject Expert)**	MBBS, FCPS General Surgery, Master Trainer CPSP Primary Surgical Skills Workshop, KEMU paper setter & assessor DPT, FCPS2 /MS Mock Examiner

14	Dr. Waqas Ilyas	**Scientific Member (Endocrinology Subject Expert)**	to be filled
15	Dr. Aneeqa Zia	**Scientific Member (Pediatrics Subject Expert)**	MBBS, FCPS in pediatrics, Consultant pediatrician Currently working as assistant professor paediatric medicine at children's hospital lahore
16	Dr. Saima Masoom	**Scientific Member (Psychology Subject Expert)**	Assistant Professor, Department of Psychology, University of Karachi. Post Doc Leicester University, UK. Supervising MPhil & PhD students, actively reviewing research for journals, and contributing to diverse research projects in psychology.
17	Dr. Shafaat Raza	**Scientific Member (Internal Medicine Subject Expert)**	MBBS, MD, Internal Medicine, MRCEM-1 Emergency Medicine, Certificate in Research and Biostatistics (CIBNP USA), Reviewer European Heart Journal. Faculty of Endocrinology and Diabetes MMCH, Ibn-e-Sina University, Mirpurkhas, Sindh.
18	Dr. Zunaira Tabassum	**Scientific Member (Gyne/ Obs Subject Expert)**	MBBS ,FCPS,MRCOG,10 plus years of experience in Obs and Gynae, case reports presented twice in RCOG world Congress(19,25),paper presented in SAFOG 2017 etc
19	Dr. Muhammad Hakim	**Scientific Member (Public Health Subject Expert)**	MBBS, MS Field Epidemiology, MCPS (Community Medicine), PG. Certificate FELTP(CDC, Atlanta USA) PhD Public Health, Khyber Medical University Peshawar. Khyber Pakhtunkhwa-Pakistan
20	Dr. Faiza Muzahir	**Scientific Member (Nephrology Expert)**	MBBS, FCPS Nephrology, Assistant Professor Jinnah Hospital Lahore

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Last Updated: Nov. 18, 2025
For more details of BMY Health Pakistan, contact admin@bmyhealth.com
Updated Policy Link:
https://docs.google.com/document/d/1CufblHjoCnyGzd2aFeJ4ippRdPBGgcLQ/edit?usp=sharing&ouid=105590562508903631713&rtpof=true&sd=true